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EXAMINER	
RAMDHANIE, BOBBY	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/567,002	HANDIQUE ET AL.	
	Examiner	Art Unit	
	BOBBY RAMDHANIE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-13,16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-5 and 9* is/are allowed.

6)☒ Claim(s) *7,8,10-13,16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 07/30/2008 was considered by the examiner on 11/28/2008.

Allowable Subject Matter

2. Claims 1, 3-5, & 9 are allowed.

3. The following is a statement of reasons for the indication of allowable subject matter: Claims 1 & 3-5, & 9 are towards a microfluidic device wherein among the recited limitations, includes a reservoir in communication with a retention member and configured to receive at least some of the first liquidic portion separated from the particles and a gate configured to open a channel downstream of the reservoir thereby decreasing the pressure within the reservoir so that at least some of the separated particles recombine with the subset of the first liquid portion separated from the particles.

4. Claim 9 is toward a microfluidic device wherein among the combination of limitations includes a reservoir in communication with the retention member configured so that a first liquidic portion of a particle-containing liquid sample received therein enters the reservoir along an entry path including a first surface of the retention member, and a gate having an open configuration wherein a subset of the first liquidic portion exits the reservoir along an exit path including the first surface of the retention member, wherein the entry path is substantially opposite the exit path.

5. The prior art of record does not disclose nor suggest these limitations.

6. The following claim 7 is drafted by the examiner and considered to distinguish patentably over the art of record in this application, Claim 7 is presented to applicant for consideration, and the amendment is required to put the method claims and subsequent microfluidic device of Claim 18 into condition for ALLOWANCE. Claims 10, 16, 18, 19, 20 are required to be amended according as well.

7. Claim 7: A method for processing a particle-containing liquidic sample, including: A). Providing a microfluidic device comprising a microfluidic network, the device comprising, including: an input port for receiving a particle-containing liquidic sample; a retention member in communication with the input port and configured to spatially separate particles of the particle-containing liquidic sample from a first portion of the particle-containing liquidic sample; and a reservoir in communication with the retention member and configured to receive at least some of the first liquidic portion separated from the particles, wherein a pressure within the reservoir increases upon receiving the first liquidic portion; and a gate configured to open a channel downstream of the reservoir thereby decreasing the pressure within the reservoir so that a pressure actuator configured to recombine at least some of the separated particles recombine with a subset of the first portion separated from the particles;

8. B). Inputting a particle-containing liquidic sample into ~~a~~ said microfluidic device ~~including a retention member including a surface~~; C). Spatially separating a first portion of the liquid of the particle-containing liquidic sample from particles of the liquidic sample by passing the first portion of the liquid through at least the surface of ~~the~~ said

retention member; and D). Recombining the retained particles with a subset of the first portion of the liquid within said microfluidic device.

Response to Arguments

9. Applicant's arguments, see Remarks, filed 06/29/2009, with respect to Claims 1, 3-5, 8, & 9 have been fully considered and are persuasive. The Claim Objection of Claim 8 and the Rejections under 102, have been withdrawn.

10. Applicant's arguments filed 06/29/2009 in regards to Claims 7-8, 10-13, 16, 18-21 have been fully considered but they are not persuasive. The following reasons are why:

11. Applicants argue that the Examiner's reason for obviousness is "not possible with the device of PARUNAK ET AL (See Page 13 of Applicants Remarks)." Applicant goes on to further describe the operation of the microfluidic device, but fails to provide any scientific or factual evidence at the time of submission of Applicant's remarks to support Applicant's argument (note: the method recited in Claims 7-8, 10-13, 16, 18-21 is broader in scope and does not require the limitations of the microfluidic device of Claim 1, which includes among the combination of limitations, that the recombination of the retained particles with a subset of the first portion of the liquid to be performed **with the microfluidic device that is recited in Claims 1, 3-5, & 9.**

12. Applicants attempt to argue that recombining the retained particles with liquid would cause dilution of the sample. This has been found unpersuasive because during the operation of the microfluidic device the particles and/or cells will still be filtered through the same retention member. Applicants have provided no scientific evidence

that the "filter paper, porous glasses, and porous gels" described in PARUNAK ET AL **do not clog (See Page 3 lines 23-27 & Page 13 lines 10-11)** and does not overcome the fact that retention members such as filter paper, porous glasses, and porous gels do clog and therefore does not overcome the Examiner's reasons for obviousness.

Response to Amendment

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claim 18 is rejected under 35 U.S.C. 102(a) as being anticipated by PARUNAK ET AL (WO03/012406).

15. Applicants claim is toward a device.

16. Regarding Claim 18, PARUNAK ET AL discloses the microfluidic device, comprising: A). A lysing chamber having a volume of less than 10 microliters (See Page 9 lines 17-18); B). An upstream channel leading to the lysing chamber and a downstream channel extending from the lysing chamber (See Figure 3); and C). A mass of a temperature responsive substance (TRS) disposed in the downstream channel, the mass of TRS configured (a) to inhibit downstream passage of material when material is introduced to the lysing chamber and (b) to pass downstream upon being heated to

allow downstream passage of material from the lysing chamber (See Page 12 lines 25-28 & Page 25 lines 1-5).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 7, 8, 10-13, 16, & 19-21 are rejected under 35 U.S.C. 103(a) as being obvious over PARUNAK ET AL.

20. Regarding Claims 7, 8, 10-13, 16, & 19-21, PARUNAK ET AL discloses the method for processing a particle-containing liquidic sample, including: A). Inputting a particle-containing liquidic sample into a microfluidic device including a retention member including a first surface (See Page 12 lines 16-20); B). Spatially separating a first portion of the liquid of the particle-containing liquidic sample from particles of the liquidic sample by passing the first portion of the liquid through at least the first surface

of the retention member (See Page 3 lines 17-20 & Page 15 lines 3-15). PARUNAK ET AL does not disclose recombining the retained particles with a subset of the first portion of the liquid. PARUNAK ET AL does disclose the use of plungers and diaphragms to act on the particles that are retained by the retention member (See Page 15 lines 10-15). It would have been obvious to one of ordinary skill in the art to incorporate “recombining the retained particles with the subset of the first portion of the liquid" because it is well known in the art that filters will clog from the particles or cells adsorbing to the surface of the filter. It would have also been obvious to one of ordinary skill in the art at the time of the invention to incorporate “recombining the retained particles with the subset of the first portion of the liquid to remove the particles or cells from the filter.

21. Regarding Claim 8, PARUNAK ET AL discloses the method of claim 7, except wherein recombining the retained particles includes reducing a pressure within the microfluidic device. PARUNAK ET AL does however disclose the method for which the pressure actuator comprises a vacuum or diaphragm. It would have been obvious to one of ordinary skill to essentially recombine at least some of the retained particles with the filtered liquid as well as with the unfiltered liquid because these devices reduce pressure within microfluidic device which would pull the particles away from the filter and recombine them with the liquid. This would lead to better efficiency of the filter (from not being clogged), prevent particles from rupturing during filtration, and reduce the filtering time of the sample.

22. Regarding Claim 10, PARUNAK ET AL discloses the method for enriching a sample, including: introducing a particle-containing fluidic sample to a microfluidic

network; applying a pressure to the fluidic sample to expel a first amount of the fluid of the fluidic sample through a filter configured to retain particles of the fluidic sample within the microfluidic network (See Page 12 lines 16-20, Page 3 lines 17-20 & Page 15 lines 3-15). PARUNAK ET AL does not disclose subjecting the first amount of the fluid retained particles of the fluidic sample to a reduced pressure to cause a portion of the first amount of the fluid to enter the microfluidic network through the filter and entrain the particles to form an enriched particle-containing sample. PARUNAK ET AL does however disclose that the retention member may be made out of a variety of materials of which include filter papers, porous glasses and porous gels.

23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of PARUNAK ET AL and subject the first amount of the fluid retained particles of the fluidic sample to a reduced pressure to cause a portion of the first amount of the fluid to enter the microfluidic network through the filter and entrain the particles to form an enriched particle containing sample because the reduced pressure would remove the particles adsorbed onto the filter back into the mixture and thus prevent clogging of the retention member.

24. Additional Disclosures Included: Claim 11: Wherein the introducing includes mating a syringe to an input port of the microfluidic network (See Page 21, lines 1-5); Claim 12: Wherein the introducing the particle-containing fluidic sample also includes the applying a pressure to expel the first amount of the fluid (See Page 15 lines 3-9); Claim 13: Wherein the subjecting the first amount of the fluid to a reduced pressure

includes creating a vacuum within the microfluidic network wherein the vacuum is in communication with the filter (See Page 15 lines 1-25).

25. Regarding Claim 16, PARUNAK ET AL discloses the method for enriching a particle-containing fluidic sample, including: Contacting the particle-containing fluidic sample with a filter so that a first amount of the fluid of the particle-containing fluidic sample passes through the filter and particles of the particle-containing fluidic sample are retained by the filter, the fluid passing through the filter entering a chamber and increasing pressure therein (See Page 12 lines 16-20 & Page 3 lines 17-20).

26. PARUNAK ET AL does not disclose allowing a portion of the first amount of the fluid to pass back through the filter and recombine with the particles retained by the filter. PARUNAK ET AL does however, disclose that the retention member may be made out of a variety of materials of which include filter papers, porous glasses and porous gels.

27. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of PARUNAK ET AL and allow a portion of the first amount of the fluid to pass back through the filter and recombine with the particles retain by the filter to remove the particles adsorbed onto the filter back into the mixture and thus prevent clogging of the retention member.

28. Regarding Claims 19-21, PARUNAK ET AL discloses the method for lysing cells of a cell-containing sample, comprising: A) Introducing the cell-containing sample to a lysing chamber of a microfluidic device (See Page 12 lines 16-20, Page 3 lines 17-20 & Page 15 lines 3-15); B). A downstream channel extending downstream from the lysing

chamber, the lysing chamber having a volume of less than 10 microliters (See Page 9 lines 17-18); C). A mass of a temperature responsive substance disposed in the downstream from the lysing chamber inhibiting downstream passage of the sample from the lysing chamber (See Page 20 lines 1-6); D). Heating cells within the lysing chamber to a temperature sufficient to release intracellular material; and E). Heating the temperature responsive substance, whereupon the temperature responsive substance and the intracellular material pass downstream (See Page 18 line 6 to Page 20 line 6 – the application of voltage to electrodes which act upon the lysis chamber invariably produces heat). PARUNAK ET AL does not explicitly disclose that the mass of a responsive substance is temperature responsive. PARUNAK ET AL does however disclose that this mass is acted upon by electrodes (See Page 20 lines 1-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the mass to be a temperature responsive mass because this would allow passage of the material of the lysing zone upon reaching a particular voltage.

29. Additional Disclosures Included: Claim 20: A method for processing a sample, comprising: introducing a particle-containing liquidic sample to a microfluidic network of a microfluidic device, wherein the introduction generates a gas pressure within a reservoir in communication with the microfluidic network the reservoir configured to receive at least some of a first liquidic portion of the particle-containing liquidic sample (See Page 3 lines 28-30 & Page 25 lines 16-20); maintaining the pressure within the reservoir; and then reducing the gas pressure within the reservoir to move a subset of the first liquidic portion within the microfluidic network (See Page 3 line 30 to Page 4 line

1 & Page 14 lines 10-12 valves are closed which maintains pressure & Page 14 line 25 to Page 15 line 2); Claim 21: Wherein reducing the gas pressure comprises heating a temperature responsive substance to open a channel within the microfluidic device network wherein the subset of the first liquidic portion can move (See Page 4 lines 1-5 & Page 25 lines 1-5 & 16-20).

Conclusion

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

31. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797